

***REMARKS***

Attached hereto on a separate sheet entitled "Version with markings to show changes made." is a version of the above amendments with the changes marked.

***Claim disposition***

Claims 3, 9, 15, and 16 are allowed.

Claims 1,7, 18-24, 27-31, and 33-37 are cancelled without disclaimer or prejudice, as explained below.

Claims 2-5, 8, 10, 11, 17, 25, 26, and 32 are amended as explained below.

New claims 38-40 are added.

Claims 2-6, 8-17, 25, 26, 32, and 38-40 are now pending in the application.

***Election/Restriction***

Claims 18-24, 27-31, and 33-37 are cancelled as set forth above, pursuant to Applicant's election of Group I, claims 1-17, 25-26, and 32 and further election of the species of SEQ ID NO:3. Applicant hereby reserves the right to file Divisional applications or take any other such appropriate measure to prosecute the invention of the non-elected claims.

**The rejection under 35 U.S.C. § 112 should be withdrawn**

Claims 1-2, 4-8, 10-14, 17, 25-26, and 32 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness.

Paragraph 4 of the Office Action indicates that the basis for this rejection of claims 1, 4, 5, 7, 10, 11, 25, 26, and 32 is the recitation of the term "substantially similar" in these claims. To facilitate allowance of the remaining claims under consideration, claims 1 and 7 are cancelled, and the dependencies in claims 4, 5, 7, 10, 11, 25, 26, and 32 are amended to be consistent with these cancellations. Accordingly, this rejection of the claims under consideration has been obviated.

Paragraph 5 of the Office Action indicates that the basis for this rejection of claims 2, 4, 5, 8, 10, 11, 25, 26, and 32 is the recitation of the term "high stringency hybridization"

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conditions" in these claims. The paragraph further indicates that the claim does not define this term and the specification , while setting forth preferences, do not set forth conditions which clearly delineate the metes and bounds. Claims 2 and 8 have been amended as set forth above, to include the recitation "...wherein said conditions comprise washing in 1% SDS, 20mM phosphate buffer and 1mM EDTA at 65°C following hybridization ...". Thus, the claims under consideration now recite specific washing conditions following any of the preferences set forth in the specification for the preceding hybridization step. See specification page 5, final paragraph. Accordingly, Applicant respectfully submits that the metes and bounds are now clearly delineated, and respectfully request that this rejection of the claims under consideration be withdrawn. Furthermore, new claims 39 and 40 are added. Support for these new claims is found throughout the specification and the original claims , for example, on page 29, lines 5-6; and on page 38, lines 20-21 respectively. In light of the above-discussed amendment of claims 2 and 8, Applicant further requests that this rejection of the claims under consideration not be extended to new claims 39 and 40.

Paragraph 6 of the Office Action indicates that claims 5, 11, and 17 are unclear in the recitation of a "host cell comprising a host cell transfected...". This apparent inadvertant typographical error is obviated by appropriate amendment.

Paragraph 7 of the Office Action indicates that claims 25, 26, and 32 are unclear in the "recitation of a SAG gene", and that "...there is nothing in the claims which distinctly claims the protein". The paragraph suggests that Applicant should "particularly point out and distinctly claim SAG gene by claiming characteristics associated with the protein." This rejection is respectfully traversed.

Applicant respectfully notes that, in contrast to these statements in the Office Action, the claims under consideration are not composition claims drawn to claiming a particular gene or protein. The claims under consideration are method claims drawn to utilizing the sequences described in the specification and recited in the claims. Applicant submits that as such, these method claims are presented with the requisite clarity. Nevertheless, to facilitate allowance of the claims under consideration, and as suggested in the Office Action, these claims are amended to exclude the recitation of [SA] and include a recitaion drawn to the characteristics associated with the protein. Thus, claims 25 and 26 now include a recitation

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drawn to "a redox-sensitive protein that protects cells from apoptosis". Claim 32 now includes a recitation drawn to "a protein having an amino acid sequences encoded by" the DNA sequences recited in the claim. Accordingly, Applicant submits that this rejection of the claims under consideration is obviated.

Paragraph 8 of the Office Action indicates that the metes and bounds of claims 25 and 26 are unclear in the term "derived from". Claims 25 and 26 are amended to now include the recitation "...primers having a sequence comprised by the DNA sequence of Claim 2, 3, 8, 9, or 15...". Thus, Applicant submits that the claims now recite primers having sequences having 100% identity to the corresponding fragment of the sequences recited in these claims. Accordingly, Applicant submits that these claims under consideration are now presented with the requisite clarity.

Paragraphs 9-10 of the Office Action indicate that claims 6 and 12-14 are rejected under 35 U.S.C. § 112, first paragraph for lack of adequate written description; the rejection being directed to insufficient deposit information in the specification, for host cells designated under ATCC.98402, 98403, 98404, and 98405. A copy of the relevant deposit receipt displaying a deposit date before the time of filing (April 10, 1997) for these accession numbers is attached herewith. Applicant respectfully requests that said receipt be made part of the record. Accordingly, Applicant respectfully requests that this rejection of the claims under consideration be withdrawn.

Paragraph 11 of the Office Action indicate that claims 1, 2, 4, 5, 7, 8, 10, 11, 25, 26 and 32 are rejected under 35 U.S.C. § 112, first paragraph for lack of adequate written description. Page 7 of the Office Action indicates that this rejection is based on the claims being broadly drawn to a DNA sequence of any size comprising a sequence that is substantially similar to, hybridize to, or are derived from SEQ ID NO:1 or 3. As stated above, claims 1 and 7 have been cancelled; and claims 2, 4, 8, 10 are amended with regard to hybridization conditions; and claims 25, 26, and 32 are amended with regard to primers being derived from a sequence. Thus, Applicant submits that this rejection of the claims under consideration is obviated in light of these claim cancellations and amendments.

Paragraph 12 of the Office Action indicate that claims 1, 2, 4, 5, 7, 8, 10, 11, 25, 26 and 32 are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement for DNA

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sequences that are substantially similar to, hybridize to, or are derived from SEQ ID NO:1 and 3. As stated above, claims 1 and 7 have been cancelled; claims 2, 4, 8, 10 are amended with regard to hybridization conditions; and claims 25, 26, and 32 are amended with regard to primers being derived from a sequence. Thus, Applicant submits that the scope of the present claims under consideration is made commensurate with the teaching in the specification, and that this rejection of the claims under consideration is obviated in light of these claim cancellations and amendments.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is respectfully solicited.

The Commissioner is hereby authorized to charge any fees under 37.C.F.R §§ 1.116 and 1.117 that may be required by this paper to Deposit Account No: 23-0455.

In the event the Examiner wishes to discuss any matter concerning this application, he is welcomed to communicate with the undersigned by telephone.

Respectfully submitted,

Dated: June 11, 2002

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Version with markings to show changes made.IN THE CLAIMS:

Claim 1 has been cancelled.

2. (Amended) An isolated and purified DNA [sequence] molecule that hybridizes to the DNA sequence shown in SEQ ID 1 under high stringency hybridization conditions wherein said conditions comprise washing in 1% SDS, 20mM phosphate buffer and 1mM EDTA at 65°C following hybridization.

4. (Amended) A recombinant DNA molecule comprising the isolated and purified DNA sequence of Claim [1] 2[,] or 3 subcloned into an extra-chromosomal vector.

5. (Amended) A recombinant host cell [comprising a host cell] transfected with the recombinant DNA molecule of Claim 4.

Claim 7 has been cancelled.

8. (Amended) An isolated and purified DNA [sequence] molecule that hybridizes to the DNA sequence shown in SEQ ID 3 under high stringency hybridization conditions wherein said conditions comprise washing in 1% SDS, 20mM phosphate buffer and 1mM EDTA at 65°C following hybridization.

10. (Amended) A recombinant DNA molecule comprising the isolated and purified DNA sequence of Claim [7,] 8[,] or 9 subcloned into an extra-chromosomal vector.

11. (Amended) A recombinant host cell [comprising a host cell] transfected with the recombinant DNA molecule of Claim 10.

17. (Amended) A recombinant host cell [comprising a host cell] transfected with a recombinant DNA molecule of Claim 16.

Claims 18-24 have been cancelled.

25. (Amended) A diagnostic assay for detecting cells containing [SAG] mutations in a gene encoding a redox-sensitive protein that protects cells from apoptosis, comprising isolating total genomic DNA from the cell and subjecting the genomic DNA to PCR amplification using primers [derived from the isolated and purified] having a sequence comprised by the DNA sequence of Claim [1,] 2, 3, [7,] 8, 9, or 15, and determining whether the resulting PCR product contains a mutation.

Claims 27-31 have been cancelled.

26. (Amended) A diagnostic assay for detecting cells containing [SAG] mutations in a gene encoding a redox-sensitive protein that protects cells from apoptosis, comprising isolating total cell RNA, subjecting the RNA to reverse transcription-PCR amplification using primers [derived from the isolated and purified] having a sequence comprised by the DNA sequence of Claim [1,] 2, 3, [7,] 8, 9, or 15 and determining whether the resulting PCR product contains a mutation.

32. (Amended) A method for purifying [SAG] a protein from bacterial cells comprising:

- a) transfected a bacterial host cell with a vector comprising the isolated and purified DNA sequence of Claim [1,] 2, 3, [7,] 8, 9, or 15 operatively linked to a promoter capable of directing gene expression in a bacterial host cell;
- b) inducing expression of the isolated and purified DNA sequence in the bacterial cells;
- c) lysing the bacterial cells;
- d) isolating bacterial inclusion bodies;

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e) purifying [SAG protein] from the isolated inclusion bodies a protein having an amino acid sequences encoded by said DNA sequence.

Claims 33-37 have been cancelled.

New claims 38 to 40 have been added as follows:

38. An isolated and purified DNA sequence encoding a polypeptide having the amino acid sequence selected from the group consisting of SEQ ID 12, SEQ ID 14, SEQ ID 22, SEQ ID 24, SEQ ID 26, SEQ ID 28, SEQ ID 30, SEQ ID 32, SEQ ID 34, SEQ ID 36, SEQ ID 38, SEQ ID 40, SEQ ID 42, SEQ ID 44, SEQ ID 46, SEQ ID 48, and SEQ ID 50.

39. The DNA molecule of claim 2, wherein said molecule encodes a polypeptide that protects a cell from apoptosis when produced in said cell.

40. The DNA molecule of claim 2, wherein said molecule encodes a polypeptide that protects against lipid peroxidation.

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## BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

### INTERNATIONAL FORM

#### RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Parke-Davis, Department of Molecular Biology  
Attn: Dr. Yi Sun  
2800 Plymouth Road  
Ann Arbor, MI 48105

Deposited on Behalf of: Warner-Lambert Company

Identification Reference by Depositor:	ATCC Designation
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Mouse cDNA encoding SAG, mSAG	98402
Human cDNA encoding SAG, hSAG-mutant1	98403
Human cDNA encoding SAG, hSAG-mutant2	98404
Human cDNA encoding SAG, hSAG	98405

The deposits were accompanied by:        a scientific description        a proposed taxonomic description indicated above.

The deposits were received April 10, 1997 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:  We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

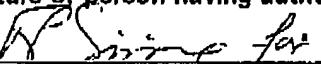
If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested April 14, 1997. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

  
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Barbara M. Hailey, Administrator, Patent Depositary

Date: April 14, 1997

cc: Todd M. Crissey (Docket 5626-01-TMC1)